



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,154	12/06/2001	Richard T. Skiffington	0656-008US6	1022
32665 7590 10/30/2008 LESLIE MEYER-LEON, ESQ. IP LEGAL STRATEGIES GROUP P.C. 1480 FALMOUTH ROAD P.O. BOX 1210 CENTERVILLE, MA 02632-1210				
EXAMINER				
BEISNER, WILLIAM H				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
10/30/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RICHARD T. SKIFFINGTON
and ELIEZER ZOMER

Appeal 2008-3855
Application 10/014,154¹
Technology Center 1700

Decided: October 30, 2008

Before BRADLEY R. GARRIS, *Administrative Patent Judge*,
FRED E. MCKELVEY, *Senior Administrative Patent Judge*, and
ROMULO H. DELMENDO, *Administrative Patent Judge*.

GARRIS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's
decision rejecting claims 1, 2, 5-7, 10, 12, 14, 15, 17-19, 23, 24, and 26.

¹ Application filed December 6, 2001, for Reissue of U.S. Patent No.
6,180,395, granted January 30, 2001, based on Application Serial No.
09/396,127, filed September 14, 1999.

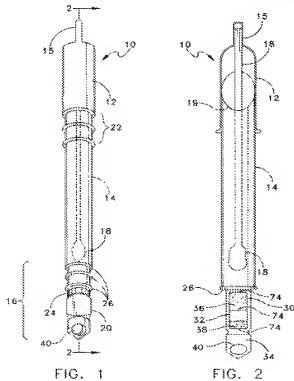
We have jurisdiction under 35 U.S.C. § 6.

We AFFIRM.

Appellants claim a unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) (claim 1), the combination of the unit dose reagent chamber in a test apparatus (claims 5, 7), and a test apparatus for the detection of ATP (claim 14).

An understanding of the claimed subject matter is facilitated by a discussion of Appellants' Figures 1 and 2 which are reproduced below:

U.S. Patent Jan. 30, 2008 Sheet 1 of 5 US 6,480,395 B1



Figures 1 and 2 show a test wand apparatus.

The test wand apparatus 10 comprises cover/plunger 12, sample unit cylinder 14, and microtube test unit 16. The cover/plunger 12 includes a swab 18 for collecting a sample to be tested for the presence of ATP. The microtube test unit includes cylindrical chambers 30, 32 which contain reagents such as a detergent-containing buffered solution for releasing ATP from the test sample on the swab into the solution for testing. The test unit also includes a bottom space 34 which contains luciferin-luciferase reagent for reaction with the released ATP in the solution.

In use, the cover/plunger 12 and swab 18 are removed from sample cylinder 14, a test sample is collected on the swab, and the cover/plunger is reinserted into the sample unit cylinder in such a way that swab 18 pierces membrane seals 74, thereby contacting the sample with the detergent-containing buffered solution to release ATP for reaction with the luciferin-luciferase reagent in bottom space 34. The reaction provides an indication of the ATP amount present in the test sample.

The claimed subject matter is adequately represented by claims 1, 5, and 7 which read as follows:

1. A unit dose reagent chamber for use in a test apparatus for the detection of adenosine triphosphate (ATP) [or alkaline phosphatase (AP)] in a test sample, and wherein a moveable probe is employed to obtain a test sample and to release reagents from the reagent chamber to a test unit, which unit dose chamber comprises:

- a) a cylinder having a one open end and an other opposite open end;
- b) a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment; and

c) a reagent composition [for use in the detection of the test sample and sealed] within the sealed compartment, which composition consists essentially of and is selected from the group consisting of:

i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) [or alkaline phosphatase (AP)] from the test sample into the solution for testing; and

ii) [a reaction stopping solution having a pH of 9 to 11; and
iii)] a luciferin-luciferase [or phosphatase substrate] reagent [tablet].

5. In combination, the chamber of claim 1 in a test apparatus for the detection of adenosine triphosphate (ATP) [or alkaline phosphatase (AP)] in a test sample, wherein the reagent composition is a detergent-containing buffered solution to release adenosine triphosphate (ATP) from the test sample into the solution for testing, which test apparatus includes a luciferin-luciferase [or phosphatase substrate] reagent for reaction with the released adenosine triphosphate (ATP) [or alkaline phosphatase (AP)] in the solution.

7. The combination of claim 5 wherein the test apparatus [includes] further comprises a closed bottom end, transparent test unit at the one end of the test apparatus, and wherein one or more unit dose reagent chambers are longitudinally positioned in the test unit.

The references set forth below are relied upon by the Examiner as evidence of obviousness:

Rich	3,666,631	May 30, 1972
Bernstein	4,770,853	Sep. 13, 1988
Simpson	EP 0 309 184	Mar. 29, 1989
Matsumoto	JP 7-59555A	Mar. 7, 1995

Claims 1, 2, 5-7, 10, and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernstein in view of Simpson and Rich, and claims 10, 14, 15, 17-19, 23, 24, and 26 are correspondingly rejected over these references and further in view of Matsumoto.

The Examiner finds that Bernstein discloses a test apparatus in combination with a reagent chamber as required by claims 1, 5, and 7 except for the claimed detergent-containing buffered solution and luciferin-luciferase reagent for respectively releasing and reacting with ATP (Ans. 3-5). In this latter regard, the Examiner also finds that the claimed solution and reagent were known to perform the claimed releasing and reacting functions in prior art ATP testing methods and apparatus (Ans. 4). Based on these findings, the Examiner concludes that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the adenosine triphosphate [ATP] detection reagents as taught by the prior art references of Simpson et al. and Rich et al. within the test device structure as disclosed by the reference of Bernstein for the known and expected result of employing an alternative means recognized in the art for storing and performing multiple step assay while providing the benefits disclosed by the reference of Bernstein when using the disclosed reagent holding system (See column 1, lines 4-28)" (*id.*).

Appellants' basic argument is that "[t]here is no motivation to combine references where, as here, the proposed modification would change the principal of operation of the prior art apparatus for the primary reference, and would render the prior art apparatus unsatisfactory for its intended purpose" (Br. 21; **bolding and italics deleted**).

ISSUE

Have Appellants established that the Examiner erred in determining one having ordinary skill in this art would have had a reason to combine

Bernstein, Simpson, and Rich in such a manner as to result in the subject matter defined by claims 1, 5, and 7?

FINDINGS OF FACT

Bernstein discloses a device for a self contained solid phase immuno-diffusion assay (Abstract). The device comprises a holder 14 having collection device 2 with tip 5 (*cf.*, Appellants' cover/plunger 12 and swab 18), cylindrical tube 13 (*cf.*, Appellants' sample unit cylinder 14), sealed reagent compartments 15, 20 (*cf.*, Appellants' reagent chambers 30, 32 having membrane seals 74), and reaction area 10 (*cf.*, Appellants' bottom space 34) (Bernstein: Figs. 1-5; col. 4, ll. 22-59). Bernstein's assay device operates similarly to Appellants' test apparatus in that tip 5 having a test sample thereon is forced downward through the seals of reagent compartments 15, 20 and into reaction area 10 where the reaction results are displayed at window 11 (*id.*). Based on a comparison of Bernstein's assay device with claims 1, 5, and 7, we share the Examiner's finding that the unit dose reagent chamber of claim 1 and the chamber/test apparatus combination of claims 5, 7 distinguish over Bernstein only by the claimed requirements for a detergent-containing buffered solution and a luciferin-luciferase reagent.

In their sole disagreement with this finding, Appellants argue that claim 7 further distinguishes over Bernstein by requiring a closed bottom end on the test apparatus (Br. 23). According to Appellants, "[t]he bottom end of the Bernstein device, in contrast, features window 11, and is not closed" (*id.*). This argument is factually erroneous. As correctly explained

by the Examiner, Bernstein's window 11 is sealed by adhesive tape 12 (col. 5, ll. 16-25), and therefore Bernstein's assay device comprises a closed bottom end (i.e., as long as adhesive tape 12 remains in place) as required by claim 7 (Ans. para. bridging 18-19). Significantly, Appellants have filed no Reply Brief contesting the Examiner's finding that Bernstein discloses the closed bottom end requirement of claim 7. As a result, Appellants ultimately do not dispute this finding in the record before us.

Appellants also do not dispute the Examiner's finding that it was known in the prior art to use the claimed detergent-containing buffered solution and luciferin-luciferase reagent for the detection of ATP as evinced by Simpson and Rich.

PRINCIPLES OF LAW

"When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).

"The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

"While it is true that the hypothetical person of ordinary skill in the art against whose knowledge the question of obviousness is weighed is *legally* presumed to know all the relevant prior art, . . . there is no

presumption, rebuttable or not, that the holder of a patent had *constructive* or *actual* knowledge of that same art when he made the invention." *In re Kleinman*, 484 F.2d 1389, 1392 (CCPA 1973).

"[O]ne cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references." *Keller*, 642 F.2d at 426.

ANALYSIS

We are unpersuaded by Appellants' argument that no reason exists for combining Bernstein with Simpson and Rich in the manner proposed by the Examiner (Br. 21). Contrary to Appellants' belief, motivation to combine these references is not negated simply because Bernstein is directed to a device for immuno-diffusion assay whereas Simpson and Rich are directed to method and apparatus for the detection of ATP. The design incentives and other market forces which prompted development of the Bernstein device (e.g., "[a] rapid, sensitive, specific, and simplistic assay is extremely useful for emergency situations, field testing, physicians offices and in home diagnostics"; col. 1, ll. 14-17) also would have prompted a variation of the device in order to make it suitable for detection of ATP regardless of whether immuno-diffusion assay and ATP testing are in the same or different fields of endeavor. *See KSR*, 127 S. Ct. at 1740.

In support of their "no motivation" argument, Appellants contend that the Examiner's proposed modification of Bernstein would change its principle of operation and would render Bernstein unsatisfactory for its intended purpose (Br. 21-22). Appellants respectively rely on *In re Ratti*, 270 F.2d 810 (CCPA 1959) and *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984)

as legal authority for this contention (*id.*). Further, Appellants refer to the second Saul Declaration (executed Sept. 28, 2005) of record as supporting their contention (App. Br. 22-23). In essence, it is the position of the Appellants and of Declarant Saul that modifying Bernstein's device to be capable of detecting ATP as proposed by the Examiner would change the device's principle of operation and render it unsatisfactory for its intended purpose because the device would no longer be capable of performing Bernstein's immuno-diffusion assay. This position is not well taken.

Appellants and Declarant Saul have confused Bernstein's immuno-diffusion assay objective with the principle of operation and the intended purpose of the Bernstein device. While the proposed modification would result in a device no longer capable of performing the immuno-diffusion assay objective, the modified device still would operate according to the same principles as the unmodified device. Specifically, whether modified or unmodified, the device would operate such that a sample would be collected on tip 5 which would be forced downward through sealed reagent compartments 15, 20 and into reaction area 10 pursuant to the operational principles taught by Bernstein. This principle of operation would not be changed in any way by replacing the immuno-diffusion assay reagents of Bernstein with the ATP detection reagents of Simpson and Rich. Analogously, the proposed modification would not render the Bernstein device unsatisfactory for its intended purpose of easily and efficiently collecting and testing a sample to be contacted with reagents in sealed compartments 15, 20 during transfer to reaction area 10. Because Appellants and Declarant Saul have confused Bernstein's immuno-diffusion

assay objective with the principle of operation and the intended purpose of the Bernstein device, the *In re Ratti* and *In re Gordon* decisions do not support the contention under review.

Regarding the proposed modification of Bernstein generally and the "closed bottom end" requirement of claim 7 specifically, Appellants argue, again with reliance on the second Saul Declaration, that "[o]ne skilled in the art would not be motivated to place a detergent containing buffered solution into the Bernstein apparatus [because] [t]he bottom of the Bernstein device is not closed, so any solution would leak out of the hole at the bottom of the test apparatus" (Br. 23). This argument is unpersuasive.

First, the argument is premised on an erroneous fact. As previously explained in the Findings of Fact section of this decision, the Bernstein device comprises a closed bottom end as required by claim 7 because window 11 is covered by adhesive tape 12. In any event, an obviousness conclusion still would be proper even if adhesive tape 12 did not cover window 11. This is because the test for obviousness is not whether the buffered solution of Simpson and Rich may be bodily incorporated into the Bernstein device; rather, the test is what the combined teachings of these references would have suggested. *See Keller*, 642 F.2d at 425. Here, the combined teachings would have suggested closing any opening in the bottom end of Bernstein's device so as to prevent the buffered solution of Simpson and Rich from leaking out of any such opening.

For the above stated reasons, a prima facie case of obviousness exists for combining Bernstein, Simpson, and Rich in such a manner as to yield the subject matter defined by argued claims 1, 5, and 7.

Appellants attempt to rebut this prima facie case of obviousness with evidence which they characterize as secondary indicia of non-obviousness. In this regard, Appellants state: "Evidence establishing a secondary indicia of non-obviousness can include evidence that others of ordinary skill in the art arrived at alternative solutions. *Monarch Knitting Machinery Corp.*, 45 USPQ2d at 1983 [sic, *Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH*, 139 F.3d 877 (Fed. Cir. 1998)]" (Br. 24). As such evidence of nonobviousness, Appellants point to U.S. Patent 5, 783,399 to Childs. The Childs patent discloses a device for detecting ATP which differs from the apparatus claimed Appellants and the device disclosed by Bernstein. Appellants argue that they are "entitled to the legal presumption that the cited references were available to Childs," and "[y]et when faced with the problem of using luciferin-luciferase to detect ATP on a test surface as an indication of bacterial contamination, the inventors of the Childs patent did not choose to modify the Bernstein reference" (Br. 25). According to Appellants, "the Childs . . . patent makes it clear that, despite [presumed] possession of the cited references, one of skill in the art would not necessarily have arrived at the solution of providing a unit dose reagent chamber containing either a detergent-containing buffered solution or a luciferin-luciferase reagent" (Br. 26). This argument lacks persuasive merit for a number of reasons.

First, *Monarch Knitting Machinery Corp.* does not support Appellants' proposition that "[e]vidence establishing a secondary indicia of non-obviousness can include evidence that others of ordinary skill in the relevant art arrived at alternative solutions" (Br. 24). *Monarch* involved

review by the Federal Circuit of a District Court's grant of summary judgment. In *Monarch*, the summary judgment grant was vacated as improper and the case was remanded back to the District Court for further proceedings. *Monarch*, 138 F.3d at 886. We find nothing and Appellants point to nothing in *Monarch* which supports the proposition that secondary evidence of non-obviousness can include evidence that others of ordinary skill in the relevant art arrived at alternative solutions.

Second, Appellants have misfocused the relevant inquiry by stating that they are "entitled to the legal presumption that the cited references were available to Childs" (Br. 25). Regardless of whether the references were "available", the relevant inquiry is whether the Childs patent inventors had constructive or actual knowledge of Bernstein, Simpson, and Rich when they made their invention. See *In re Kleinman*, 484 F.2d at 1392. The record before us contains no evidence that the Childs inventors had constructive or actual knowledge of these references. To the contrary, the absence of such knowledge is evinced by the fact that none of these references is listed in the Childs patent as having been considered during prosecution. For these reasons, the Childs patent has no probative value as to what Bernstein, Simpson, and Rich would or would not have suggested to those with ordinary skill in this art.

In light of the foregoing, we determine that Bernstein, Simpson, and Rich establish a prima facie case of obviousness for argued claimed 1, 5, and 7 which Appellants have failed to successfully rebut with their argument and evidence for non-obviousness.

In discussing the other rejection on appeal which additionally relies on the Matsumoto reference, Appellants merely list alleged deficiencies of Matsumoto considered individually and then refer to the argument and evidence discussed above with respect to Bernstein, Simpson, and Rich (Br. 27). However, Appellants cannot show nonobviousness by attacking Matsumoto individually since the rejection is based on a combination of references. *See Keller*, 642 F.2d at 426. Moreover, the argument and evidence advanced against Bernstein, Simpson, and Rich do not establish non-obviousness for the reasons fully detailed above. Finally, our study of Matsumoto reveals nothing inconsistent with the above discussed rejection based on Bernstein, Simpson, and Rich.

CONCLUSION OF LAW

The argument and evidence advanced by Appellants in this record fail to establish error in the Examiner's determination that an artisan would have been motivated to combine Bernstein, Simpson, and Rich in the proposed manner.

Therefore, we sustain the § 103 rejections of claims 1, 2, 5-7, 10, and 12 as being unpatentable over Bernstein, Simpson, and Rich, and of claims 10, 14, 15, 17-19, 23, 24, and 26 as being unpatentable over these references and further in view of Matsumoto.

ORDER

The decision of the Examiner is affirmed.

Application 10/014,154
Appeal No. 2008-3855

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

cam

LESLIE MEYER-LEON, ESQ.
IP LEGAL STRATEGIES GROUP, P.C.
1480 FALMOUTH ROAD
P O BOX 1210
CENTERVILLE, MA 02632-1210